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VIA EXPRESS MAIL

April 1, 1994

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

Petition for Reconsideration

RE: Docket No. 92E-0133 - Supprelin
Application for Patent Term Extension
Our File No. 37972 (3052)

Dear Sir:

Reconsideration is petitioned with respect to the denial of the Request for Redetermination of the period for the testing phase of Supprelin, as set forth in the letter of Stuart L. Nightingale, M.D. dated March 8, 1994.

It is believed that the FDA, in determining such a testing period for purposes of patent term extension, has decided to formulate an overall procedure to be followed in all cases in order to avoid having to make individual determinations based upon an assessment of the facts in each particular case. While it is acknowledged that such a procedure would ease the administrative burden on the FDA, it is submitted that justice is not done in the present case when the facts of the situation are ignored with respect to the regulatory review period for

92E-0133

PRC 1

Supprelin prior to permitting its marketing for the treatment of precocious puberty. Attached is a copy of our July 16, 1992, Request for Redetermination, reconsideration of the denial of which is hereby petitioned.

We wish to emphasize that the regulatory review period in question is that particular regulatory review pertinent to the first permitted commercial marketing or use of the product as set forth in 35 U.S.C. §1.156(a)(5)(A). It is specifically pointed out in 35 U.S.C. §1.156(c) that the patent term shall be extended "by the time equal to the regulatory period for the approved product", and it is clear that the product was approved for treatment only of precocious puberty--not for treatment of endometriosis. It is perfectly clear that the class of patients suffering from precocious puberty is totally different from the class of patients suffering from endometriosis; therefore, the response of patients taking part in a clinical study for treatment of endometriosis would be in no way relevant with respect to treatment for the indication of precocious puberty.

The unwarranted extension of the regulatory period to include the time when there was an investigation by a different investigator for a totally different indication, i.e. endometriosis, results (under the peculiar circumstances of the present case) in unfairly shortening the patent term extension. It thus works to the considerable detriment of the patentee, The Salk Institute for Biological Studies, a well-known, not-for-profit organization.

In view of the foregoing, this petition is being filed for reconsideration by the F.D.A. of the denial of Salk's request to limit the regulatory review periods to those when investigation was proceeding with regard to the only indication for which regulatory approval has been given, namely the use for treatment of precocious puberty. A redetermination of the period of the testing phase to constitute the time period from about

December 24, 1984, through May 23, 1989, i.e. about 1,609 days, is respectfully requested.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY for
THE SALK INSTITUTE FOR BIOLOGICAL STUDIES

By: James J. Schumann

Enclosure

JJS/lm

bcc: D. Dale Busch (w/o encl)
Joseph J. Brindisi (w/o encl)

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July 16, 1992

VIA EXPRESS MAIL

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

RE: Request for Redetermination
Supprelin - Docket No. 92E-0133
Application for Patent Term Extension
Our File No. 52510 (3052)

Dear Sir:

A Notice was published in the Federal Register on Tuesday, June 2, 1992, pertinent to the application for the patent term extension of U.S. Patent No. 4,244,946, which was filed on behalf of The Salk Institute for Biological Studies. Redetermination of the regulatory review period for Supprelin, with particular respect to the period of the testing phase, is respectfully requested.

In Paragraph 1 of the Notice with respect to the derivation of these time periods, it is indicated that no IND effective date was stated by Applicant in its application for patent term extension; however, this is incorrect for on page 7 of the application, it was stated that a pertinent IND was submitted by Dr. Ora Pescovitz in November 1985 and assigned No. 27,427.

Presumably, the reference in the Notice being made to "the IND" was directed to a related (but not pertinent) IND of Ortho Pharmaceutical Corporation (IND No. 23,307) that was

submitted in early 1984. The date of this IND of Ortho's was expressly not indicated in the application because the IND of Ortho was for a different use of the drug product, namely the treatment of endometriosis, not precocious puberty.

The investigational work leading up to the filing of the new drug application for Supprelin was done by independent investigators sponsored by Ortho, and it is not believed that Ortho ever filed an IND for the use of histrelin (Supprelin) for treatment of precocious puberty. Attached are copies of pages 5 through 12 of the application for patent term extension which point out that reliance in the Ortho NDA was placed on the INDs of a group of independent investigators, primarily upon the studies conducted under the INDs of Drs. William Crowley and Ora Pescovitz. Although these two doctors were authorized to cross refer to Ortho's existing IND for purposes of chemistry, toxicology and the like, it was their independent studies carried out pursuant to these two INDs which constituted the pertinent investigational work with respect to the administration of histrelin (Supprelin) for the treatment of precocious puberty.

As pointed out on page 5, Dr. Crowley's IND had originally been issued to permit investigation using a different chemical compound, namely, the native hormone GnRH. The FDA was subsequently requested, on about December 24, 1984, to modify the original IND to permit the administration of histrelin for the treatment of precocious puberty.

Concurrently with the work of Dr. William Crowley, Dr. Ora Pescovitz submitted an IND that was received by the FDA on about November 15, 1985, and assigned No. 27,427. When the NDA for Supprelin for the treatment of precocious puberty was submitted by Ortho, it was premised upon the work done by Dr. Ora Pescovitz under IND No. 27,427 and the work done by Dr. William Crowley under his modified IND No. 13,353 as constituting the principal test data, although reference was also made to

additional testing that had been carried out by other independent investigators who were also sponsored by Ortho and who were listed on page 6 of the attached material.

Therefore, it is submitted that the statement in the Notice that the "the IND effective date was February 8, 1984" is in error and should be changed. The date upon which an IND was first effective to permit the use of histrelin (Supprelin) for investigation for the treatment of precocious puberty should be no earlier than about December 24, 1984, when Dr. William Crowley requested a modification of his existing IND. Such was believed to constitute the first request under the sponsorship of Ortho for formal permission to investigate the use of histrelin for the treatment of precocious puberty. If the date of modification of the existing IND of Dr. William Crowley should for some reason be inappropriate, then the date of about November 15, 1985 for IND No. 27,427 of Dr. Pescovitz should be chosen as the appropriate date.

It is accordingly requested that the period of time occurring during the testing phase as determined by the FDA, namely 2876 days, be redetermined. The testing phase should be held to constitute a period from about December 24, 1984 through May 23, 1989, i.e., about 1609 days. The determination of the approval phase as constituting 946 days is accepted.

Very truly yours,

FITCH, EVEN, TABIN & FLANNERY for
THE SALK INSTITUTE FOR BIOLOGICAL STUDIES

By: James J. Schumann
James J. Schumann

Enclosure

JJS/lm